

Claims

1. A process for the production of biodegradable polymer particles which comprises:
 - 5 a) introduction of at least one inducible gene into a microorganism, wherein the gene codes for a protein which controls the size of the polymer particles; and
 - b) cultivation of the microorganism with induction of the at least one inducible gene stated in a) in a culture medium under conditions which
10 are suitable for the production of the biodegradable polymer particles by the microorganism.
2. A process according to claim 1, wherein, in stage a), apart from the at least one inducible gene which codes for a protein which controls the size of the polymer
15 particles, at least one further gene which codes for a protein involved in the formation of the polymer particles is introduced.
3. A process according to claim 2, wherein the at least one further gene which codes for a protein involved in the formation of the polymer particles codes for a
20 thiolase, a reductase or a polymer synthase.
4. A process according to claim 3, wherein the at least one further gene which codes for a protein involved in the formation of the polymer particles codes for
25 phaA thiolase, phaB ketoacyl reductase or phaC synthase from *Ralstonia eutropha*.
5. A process according to any one of the preceding claims, wherein the at least one inducible gene which codes for a protein which controls the size of the polymer
30 particles is derived from the family of phasin-like proteins.
6. A process according to claim 5, wherein the at least one inducible gene which codes for a protein which controls the size of the polymer particles is selected

from the group comprising the phasin gene phaP from *Ralstonia eutropha* and the phasin gene phaF from *Pseudomonas oleovorans*.

- 5 7. A process according to any one of the preceding claims, wherein at least one additional gene which codes for a thiolase and/or a polymer synthase is introduced into the cell.
8. A process according to any one of the preceding claims, wherein at least one fatty acid with functional side groups and particularly preferably at least one
10 hydroxy fatty acid and/or at least one mercapto fatty acid and/or at least one β -amino fatty acid is introduced into the culture medium as a substrate for the formation of the polymer particles.
9. A process according to any one of the preceding claims, wherein the substrate is
15 added to the culture medium in such a quantity that it is sufficient to ensure control of the size of the polymer particles.
10. A process according to any one of the preceding claims, wherein the
20 microorganism used is selected from the genera comprising *Ralstonia*, *Alcaligenes*, *Pseudomonas* and *Halobiforma*.
11. A process according to claim 10, wherein the microorganism used is selected
25 from the group comprising *Ralstonia eutropha*, *Alcaligenes latus*, *Escherichia coli*, *Pseudomonas fragi*, *Pseudomonas putida*, *Pseudomonas oleovorans*, *Pseudomonas aeruginosa*, *Pseudomonas fluorescens*, and *Halobiforma haloterrestris*.
12. A process according to any one of the preceding claims, wherein the cultivated
30 microorganisms are disrupted in per se known manner and the polymer particles then separated from the cell debris.

13. A process according to claim 12, wherein a lipid layer located on the surface of the polymer particles is separated from the polymer particles obtained according to the process of claim 12 and replaced by a lipid layer of another composition.
- 5 14. A process according to any one of the preceding claims, wherein particle size is controlled by the at least one inducible gene in such a manner that the polymer particles formed have a diameter of 10 nm to 3 μ m, preferably a diameter of 10 nm to 900 nm, and particularly preferably a diameter of 10 nm to 100 nm.
- 10 15. A process according to claim 1 or claim 2, wherein the at least one inducible gene introduced in stage a) which codes for a protein which controls the size of the polymer particles comprises a polymer particle binding domain and at least one binding domain, wherein the at least one binding domain is capable of binding a biologically active substance and/or a coupling reagent.
- 15 16. A process according to claim 2, wherein the at least one further gene introduced in stage a) which codes for a protein involved in the formation of the polymer particles comprises a polymer particle binding domain and at least one binding domain, wherein the at least one binding domain is capable of binding a
- 20 biologically active substance and/or a coupling reagent.
17. A process according to claim 15 or claim 16, wherein the polymer particle binding domain comprises part of a protein bound to the surface of the polymer particle, wherein the protein is selected from the group comprising a polymer depolymerase, a polymer regulator, a polymer synthase and a particle size-
- 25 controlling protein.
18. A process according to claim 15, 16 or 17, wherein the at least one binding domain which is capable of binding a biologically active substance and/or a
- 30 coupling reagent is selected from the group comprising oligopeptides, enzymes, abzymes or non-catalytic proteins.

19. A process for the *in vitro* production of biodegradable polymer particles which comprises:
- a) provision of a solution suited to polymer particle formation with at least one substrate;
 - 5 b) introduction into the solution of a protein which is suited to controlling the size of the polymer particles; and
 - c) introduction of at least one further protein which is involved in the formation of the polymer particles.
- 10 20. A process according to claim 19, wherein at least one fatty acid and an acyl CoA oxidase is added to the solution suited to polymer particle formation in stage a) for the formation of the polymer particles.
- 15 21. A process according to any one of claims 19 or 20, wherein, in stage a), at least one substrate is added to the solution suited to polymer particle formation in such a quantity that it is sufficient to ensure control of the size of the polymer particles.
- 20 22. A process according to claims 19 to 21, wherein, in stage b), a polymer particle size-controlling protein is introduced which is derived from the family of phasin-like proteins.
- 25 23. A process according to claim 22, wherein, in stage b), a polymer particle size-controlling protein is introduced which is selected from the group comprising the phasin from *Ralstonia eutropha* and the phasin from *Pseudomonas oleovorans*.
- 30 24. A process according to any one of claims 19 to 23, wherein the at least one further protein involved in polymer particle formation used in stage c) is a polymer synthase.
25. A process according to claim 24, wherein the at least one further protein involved in polymer particle formation used in stage c) is a polymer synthase

which is selected from the group comprising the polymer synthase from *R. eutropha*, *P. oleovorans*, *P. putida* and *P. aeruginosa*.

26. A process according to claim 26 or claim 27, wherein the polymer synthase is added to the solution in such a quantity that it is sufficient to ensure control of the size of the polymer particles.

27. A process according to any one of claims 21 to 26, wherein, in stage a), at least one pharmaceutically active substance is added to the solution.

28. A process according to any one of claims 21 to 29, wherein, in order to control the composition of the lipid layer on the surface of the polymer particle, at least one amphiphilic molecule from the group of phospholipids and ether lipids is added to the solution from step a).

29. A process according to any one of claims 19 to 28, wherein at least one of the proteins introduced in stages b) and c) is selected such that it comprises a polymer particle binding domain and at least one binding domain, wherein the at least one binding domain is capable of binding a biologically active substance and/or a coupling reagent.

30. A process according to claim 29, wherein the polymer particle binding domain is part of the protein bound to the surface of the polymer particle, wherein the protein is selected from the group comprising a polymer depolymerase, a polymer regulator, a polymer synthase and a particle size-controlling protein.

31. A process according to claim 29 or claim 30, wherein the at least one binding domain which is capable of binding a biologically active substance and/or a coupling reagent is selected from the group comprising oligopeptides, enzymes, abzymes or non-catalytic proteins.

32. A polymer particle of defined size, with a surface layer of amphiphilic molecules, into which [is introduced] at least one protein which is selected from

the group comprising a polymer depolymerase, a polymer regulator, a polymer synthase and a particle size-influencing protein, wherein the at least one protein comprises a polymer particle binding domain and a binding domain which is capable of binding a biologically active substance and/or a coupling reagent.

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33. A polymer particle according to claim 32, produced according to a process described in claims 1 to 33.

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34. Use of the polymer particles according to claims 32 or 33 for the production a pharmaceutical preparation, a pesticide or a herbicide.

35. Use according to claim 34, wherein the pharmaceutical preparation is suitable for the treatment of diseases of the central nervous system.